DEPART

Drug Enforcement Administration

[Docket No. DEA-751]

Importer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen Pharmaceuticals Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on November 11, 2020, Janssen Pharmaceuticals Inc., 1440 Olympic Drive,

Athens, Georgia 30601-1645, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Thebaine	9333	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import intermediate forms of Tapentadol (9780) and Thebaine (9333) for further manufacturing prior to distribution to its customers. The company plans to import Poppy Straw Concentrate (9670) to bulk manufacture other controlled substances. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,
Assistant Administrator.

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